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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,228	03/16/2004	Michael N. Helmus	03-089	2014
27774 7590 01/07/2008 MAYER & WILLIAMS PC 251 NORTH AVENUE WEST 2ND FLOOR WESTFIELD, NJ 07090				
			EXAMINER GHALI, ISIS A D	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 01/07/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/801,228	<b>Applicant(s)</b> HELMUS ET AL.	
	<b>Examiner</b> Isis A. Ghali	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 11-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/16/04; 3/16/05; 8/10/05</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The receipt is acknowledged of applicants' election filed 10/19/2007, IDS filed 08/10/2005; IDS filed 03/16/2005; and IDS filed 03/16/2004.

Claims 1-23 are pending.

#### ***Election/Restrictions***

1. Applicant's election without traverse of invention II and species stent graft, claims 1, and 4-10 in the reply filed on 10/19/2007 is acknowledged.
2. Claims 2, 3, 11-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/19/2007.

Claims 1, 4-10 are included in the prosecution.

#### ***Specification***

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 6,545,097 ('097) and US 4,475,972 ('972).

US '097 teaches intravascular medical device for implantation in the body of patient comprises biocompatible block copolymer (abstract). the block copolymer preferable comprises isobutylene block and styrene block (col.1, line 65-col.2, line 3; col.21, lines 1-14). The block copolymer has the advantage of having high tensile

strength, resists cracking and degradation under in vivo condition, and exhibits excellent vascular compatibility and ability to minimize thrombotic occlusion of small vessels (col.5, lines 15-29). The devices are produced by forming solution of the block copolymers that undergoes spinning and can be in the form of fibers, the reference disclosed drying of block copolymer by solvent evaporation (col.14, lines 30-37, 47-63). Medical devices produced by the disclosed block copolymers are porous and tubular and including stent graft (col.13, line 59; col.14, line 63; col.15, lines 6-8).

Although US '097 suggested spinning of polymer solution, and fiber formation, and evaporation of solvent, however, the reference does not explicitly teach fibers formed by dry spinning as claimed by claim 1. The reference does not teach fibers forming woven and non-woven regions as claimed by claims 5 and 6, or the fibers are thermally bonded as claimed by claim 7 and 8.

US '972 teaches tubular porous biocompatible polymer suitable for vascular devices (abstract). The device is produced by spinning solution of the polymer and the solvent is evaporated by heat during winding of the filaments, i.e. dry spinning (col.4, lines 3-15). Evaporation of the solvent provides non-woven structure (col.3, line 12; col.4, lines 8-10; col.5, lines 43-46). Woven structures also disclosed (col.5, line 33). The fibers are bonded together upon evaporating the solvent (col.1, lines 35-38; col.4, lines 5-7). The method of dry spinning provides improved procedure for formation of porous tubular material suitable for medical vascular devices having high suturing strength and high toughness to resist cyclic fatigue (col.1, lines 33-50).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical device comprises block copolymer of polyisobutylene and styrene that can be in the form of fibers as disclosed by Us '097, and produce the fibers by dry spinning that provide fiber to fiber bonding as disclosed by US '972 because US '972 teaches that such a method provides improved procedure for formation of porous tubular material suitable for medical vascular devices having high suturing strength and high toughness to resist cyclic fatigue, with reasonable expectation of having tubular porous medical device comprises block copolymer of polyisobutylene and styrene fibers produced by dry spinning that have high suturing strength and high toughness to resist cyclic fatigue.

Vise versa, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide tubular porous vascular medical device comprises biocompatible fibers produced by dry spinning as disclosed by US '972, and replace the biocompatible polymer with the block copolymer comprising isobutylene and styrene disclosed by US '097 because US '097 disclosed such block copolymer has the advantage of high tensile strength, resists cracking and degradation under in vivo condition, and exhibits excellent vascular compatibility and ability to minimize thrombotic occlusion of small vessels, with reasonable expectation of having tubular porous vascular medical device comprises biocompatible fibers of block copolymers of styrene and isobutylene produced by dry spinning that has high tensile strength, resists cracking and degradation under in vivo condition, and exhibits excellent vascular compatibility and ability to minimize thrombotic occlusion of small vessels.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali  
Primary Examiner  
Art Unit 1615

IG



ISIS GHALI  
PRIMARY EXAMINER